Attorney's Docket No.: 16614-030001 / 0054.13

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant	: Thomas E. Tarara et al.	Art Unit	: 1616
Serial No.	: 10/612,393	Examiner	: Sharmila S. Gollamudi
Filed	: July 3, 2003		
Title	: ENGINEERED PARTICLES AND METHODS OF USE		

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Commissioner for Patents
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Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT

Applicants request consideration of the references listed on the attached PTO-1449 form. Under 37 C.F.R. § 1.98 (a)(2)(ii), only copies of foreign patent documents and/or non-patent literature are enclosed. Copies of any listed U.S. patents or U.S. patent application publications can be provided upon request.

This filing is being made with the filing of a Request for Continued Examination. No fee is required.

Respectfully submitted,

Date: May 9, 2006

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Substitute Form PTO-1449 (Modified)	U.S. Department of Commerce Patent and Trademark Office	Attorney's Docket No. 16614-030001	Application No. 10/612,393
Information Disclosure Statement by Applicant (Use several sheets if necessary) (37 CFR §1.98(b))		Applicant Thomas E. Tarara et al.	
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Examiner Initial	Desig. ID	Document Number	Publication Date	Patentee	Class	Subclass	Filing Date If Appropriate
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	A2	2002/0132787	09/2002	Eljamal et al.			
	A3	2002/0192164	12/2002	Patton et al.			
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	A154	5775320	07/1998	Patton et al.			
	A155	5780014	07/1998	Eljamal et al.			
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	A170	6019968	02/2000	Platz et al.			
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	A176	6123924	09/2000	Mistry et al.			
	A177	6123936	09/2000	Platz et al.			
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	B66	93/10758	06/1993	WO				
	B67	93/11746	06/1993	WO				
	B68	93/12240	06/1993	WO				

Examiner Signature	Date Considered
EXAMINER: Initials citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	

Substitute Form PTO-1449 (Modified)	U.S. Department of Commerce Patent and Trademark Office	Attorney's Docket No. 16614-030001	Application No. 10/612,393
Information Disclosure Statement by Applicant (Use several sheets if necessary) (37 CFR §1.98(b))		Applicant Thomas E. Tarara et al.	
		Filing Date July 3, 2003	Group Art Unit 1616

Foreign Patent Documents or Published Foreign Patent Applications

Examiner Initial	Desig. ID	Document Number	Publication Date	Country or Patent Office	Class	Subclass	Translation Yes	Translation No
	B69	93/13752	07/1993	WO				
	B70	93/17663	09/1993	WO				
	B71	93/23065	11/1993	WO				
	B72	93/23110	11/1993	WO				
	B73	94/07514	04/1994	WO				
	B74	94/13271	06/1994	WO				
	B75	94/22423	10/1994	WO				
	B76	94/24263	10/1994	WO				
	B77	95/00127	01/1995	WO				
	B78	95/01324	01/1995	WO				
	B79	95/06126	03/1995	WO				
	B80	95/20979	08/1995	WO				
	B81	95/24183	09/1995	WO				
	B82	95/31479	11/1995	WO				
	B83	95/33488	12/1995	WO				
	B84	96/03978	02/1996	WO				
	B85	96/09085	03/1996	WO				
	B86	96/27393	09/1996	WO				
	B87	96/32096	10/1996	WO				
	B88	96/40049	12/1996	WO				
	B89	96/40077	12/1996	WO				
	B90	97/26863	07/1997	WO			Abstr.	
	B91	97/34689	09/1997	WO				
	B92	98/24882	06/1998	WO				
	B93	98/58989	12/1998	WO				
	B94	01/87278	11/2001	WO				

Other Documents (include Author, Title, Date, and Place of Publication)

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Attorney's Docket No.: 16614-030001 / 0054.13

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant	: Thomas E. Tarara et al.	Art Unit	: 1616
Serial No.	: 10/612,393	Examiner	: Sharmila S. Gollamudi
Filed	: July 3, 2003		
Title	: ENGINEERED PARTICLES AND METHODS OF USE		

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Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

AMENDMENT IN REPLY TO ACTION OF FEBRUARY 9, 2006

Please amend the above-identified application as follows:

Amendments to the Claims:

This listing of claims replaces all prior versions and listings of claims in the application:

Listing of Claims:

1. (canceled)

2. (withdrawn) A composition comprising microspheres, wherein said microspheres have a wall thickness of 100 to 500 nm, and a bulk density of no more than 0.1 g/cm^3.

3. (withdrawn) The composition according to claim 2, wherein the mean geometric particle size of said microspheres is less than 20 μm.

4. (withdrawn) A composition comprising microspheres, wherein said microspheres have a wall thickness of 43.5 to 261 nm.

5. (withdrawn) The composition according to claim 2 wherein the walls of said microspheres comprise albumin.

6. (withdrawn) The composition according to claim 2 obtainable by spray-drying a wall-forming material in combination with a blowing agent.

7. (withdrawn) The composition according to claim 2 wherein said microspheres comprise a bioactive agent.

8. (withdrawn) The composition according to claim 7, wherein said microspheres comprise a protein or peptide.

9. (withdrawn) The composition according to claim 7, wherein said microspheres comprise an active agent selected from the group consisting of insulin, growth hormone and interferon.

10. (withdrawn) An inhaler comprising an inhalable formulation of microspheres wherein said microspheres have a wall thickness of 100 to 500 nm, and a bulk density of no more than 0.1 g/cm^3 and wherein said microspheres comprise a bioactive agent.

11. (withdrawn) The inhaler according to claim 10, wherein the formulation comprises the microspheres as the sole or the predominant component thereof.

12. (withdrawn) A method for pulmonary administration of a bioactive agent wherein said method comprises the administration to the lungs of a composition which comprises microspheres having a wall thickness of 100 to 500 nm and a bulk density of no more than 0.1 g/cm^3, wherein said microspheres further comprise a bioactive agent.

13. (withdrawn) The method according to claim 12, wherein the mean geometric diameter of said microspheres is less than 20 μm.

14. (withdrawn) A method for pulmonary administration of a bioactive agent wherein said method comprises the administration to the lungs of a composition which comprises microspheres having a wall thickness of 43.5 to 261 nm and a bulk density of no more than 0.1 g/cm^3, wherein said microspheres further comprise a bioactive agent.

15. (withdrawn) The method according to claim 12, wherein the walls of said microspheres comprise albumin.

16. (withdrawn) The method according to claim 12, wherein said microspheres are obtainable by spray-drying a wall-forming material, in combination with a blowing agent.

17. (withdrawn) The method according to claim 12, wherein said microspheres comprise a

protein or peptide.

18. (withdrawn) The method according to claim 12, wherein said microspheres contain a bioactive agent selected from the group consisting of insulin, growth hormone and interferon.

19. (withdrawn) A method for diagnosis wherein said method comprises administering to a patient in need of such diagnosis, a composition which comprises microspheres having a wall thickness of 100 to 500 nm and a bulk density of no more than 0.1 g/cm^3.

20. (withdrawn) The method according to claim 19, wherein the mean geometric diameter of said microspheres is less than 20 μm.

21. (withdrawn) A method for diagnosis wherein said method comprises administering to a patient in need of such diagnosis, a composition which comprises microspheres having a wall thickness of 43.5 to 261 nm and a bulk density of no more than 0.1 g/cm^3.

22. (withdrawn) The method according to claim 19, wherein the walls of said microspheres comprise albumin.

23. (withdrawn) The method according to claim 19, wherein said microspheres are obtainable by spray-drying a wall-forming material, in combination with a blowing agent.

24. (currently amended) A method for preparing microparticles, wherein said method comprises spray-drying wall-forming materials to form said microparticles, wherein said microparticles have a wall thickness of about 100 to 500 nanometers, said ~~wall-foming~~ wall-forming materials include a therapeutic bioactive agent and said method further comprises inclusion of a blowing agent in the feedstock for spray-drying.

25. (previously presented) The method according to claim 24, wherein said blowing agent is selected from the group consisting of ammonium acetate and ammonium carbonate.

26. (previously presented) The method according to claim 24, wherein said wall-forming material is albumin.

27. (withdrawn) A composition comprising microspheres, wherein said microspheres have a wall thickness of 100 to 500 nm, and a bulk density of no more than 0.3 g/cm^3.

28. (withdrawn) The composition according to claim 2 wherein the bulk density is no more than 0.05 g/cm^3.

REMARKS

Claim Amendments

Claim 24 has been amended to correct a typographical error.

Information Disclosure Statement

Some of the references in the Information Disclosure Statement of November 9, 2005, were not considered. The applicant submits herewith an Information Disclosure Statement with the references that were previously not submitted along with additional references. The applicant requests that the Examiner review the submitted references, initial the PTO-1449 and return the initially PTO-1449 to the applicant.

Rejections Under Section 103

Claims 24 and 26 were rejected under 35 U.S.C. § 103(a) as being unpatentable over WO 92/18164 ("Sutton") in view of WO 96/15814 ("Osborne"). The applicant respectfully traverses.

Claim 24 is directed to a method for preparing microparticles. The method comprises spray-drying wall-forming materials. The wall-forming materials include a therapeutic bioactive agent. The method further comprises inclusion of a blowing agent in the feedstock for spray-drying. Claim 26 depends from claim 24.

Sutton describes preparing microcapsules from albumin (Abstract). The microcapsules are injected into a patient and are allowed to flow through the heart, lungs and veins (page 18, lines 13-20). Ultrasonic scanning equipment is used to image the microcapsules in the body to show unusual blood flow within the heart, valvular competence, chamber size, wall motion and indications of myocardial perfusion (page 17, line 21-page 19, line 11). As noted by the Examiner, Sutton does not teach a blowing agent or a bioactive agent as an additive in a spray drying solution.

Osborne describes a process for forming microcapsules from albumin for ultrasound echogenic contrast agents (Abstract). Osborne also fails to teach using a bioactive agent.

Both Sutton and Osborne fail to suggest or disclose therapeutic agents or spray-drying wall-forming materials including a therapeutic bioactive agent therapeutic bioactive agent to form a microparticle. Applicant agrees with the Examiner that "Sutton does not specify the use of a blowing agent or a bioactive agent as the additive in the spray drying solution" (Office Action page 4). However, the applicant does not agree with the Examiner's rejection based on the teachings of Sutton. The Examiner argues that "One would have been motivated to add a bioactive agent such as a contrast agent or a magnetic resonance imaging agent to the spray solution. A skilled artisan would have been motivated to do so since Sutton teaches the microcapsules are utilized for imaging areas in the body and the inclusion of a contrast agent or a magnetic resonance imaging agent would further enhance the imaging process" (Office action, pages 5-6). The applicant respectfully disagrees with the Examiner's interpretation of a contrast agent or a magnetic resonance imaging agent as a bioactive agent. While these agents enable a scanner to image the agent within the body, these agents are not necessarily bioactive. Further, the Examiner has ignored the adjective "therapeutic", as required by claim 24. A contrast agent or a magnetic resonance imaging agent is not intended to be therapeutic, but is rather used to help diagnose or monitor a patient's condition. Thus, both Sutton and Osborne fail to suggest using a therapeutic bioactive agent. Moreover, nothing in Sutton or Osborne would motivate one to add a therapeutic bioactive agent to the microcapsules of either Sutton or Osborne or a combination thereof. Thus, applicant submits that no *prima facie* case of obviousness has been made with respect to claims 24 and 26.

In addition, claim 39 of U.S. Patent No. 6,416,739 ("Rogerson") recites a method for preparing microparticles, wherein the method comprises spray-drying wall-forming materials and inclusion of a blowing agent in the feedstock for spray-drying. Claim 39 includes some of the limitations of applicant's claim 24. According to the Examiner's arguments, Sutton and Osborne could have been used to reject Rogerson's claim 39. Accordingly, the office action including the rejection of applicant's claims should have been signed by the TC Director (See MPEP § 1003).

Claim 25 is rejected as being unpatentable over Sutton in view of Osborne in view of U.S. Patent No. 2,797,201 ("Veatch"). The applicant respectfully disagrees.

Claim 25 depends from claim 24 and necessarily includes the limitations of claim 24.

Veatch describes making hollow particles for low density products, such as linoleum and floor tile, as aggregate in concrete and plaster, plastic foam, gaskets, seals, buoys, flotation equipment, boat hulls and other items (col. 10, lines 27-49).

Veatch does not suggest or disclose a therapeutic bioactive agent. Because each of Sutton, Osborne and Veatch fail to suggest or disclose spray-drying wall-forming materials including a therapeutic bioactive agent therapeutic bioactive agent to form a microparticle, applicant respectfully submits that no *prima facie* case of obviousness has been made for claim 25.

Moreover, Veatch could have been used to reject claim 39 of Rogerson. Veatch describes forming particles with sizes of about 25-250 microns, out of film forming material and a blowing agent (col. 2, lines 21-41, col. 3, lines 4-29, col. 4, lines 65-67). Spray drying is used to form the particles (col. 4, lines 4-7). Because Veatch could have been used to reject claim 39 in Rogerson, the office action including the rejection should have been signed by the TC Director (See MPEP § 1003).

Claims 24 and 25 are rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. 3,957,964 ("Grimm") in view of U.S. Patent No. 4,180,593 ("Cohan") or vice-versa. The applicant respectfully disagrees.

Grimm describes forming dentifrice, or toothpaste, having encapsulating shells or coatings therein (Abstract). The encapsulating material can be a synthetic organic polymeric plastic (col. 3, lines 38-41). Materials that might be unstable when distributed throughout the dentrifice, such as fluorides, antibiotics, bactericides and colorants, are encapsulated for release when a user brushes with the dentifrice (col. 2, lines 9-13 and 68 and col. 3, lines 1-28). When chemical interactions with the material are to be avoided, the encapsulation provides a barrier between the encapsulated material and the dentrifrice matrix (col. 3, lines 1-27).

Cohan describes forming blown beads which comprise an edible film forming food material (col. 2, lines 14-18).

Both Grimm and Cohan fail to teach or suggest spray-drying wall-forming materials that include a therapeutic bioactive agent. Grimm suggests forming capsules that have antibiotics surrounded by a wall of polymeric plastic. Grimm encapsulates a nucleus of antibiotics, or other unstable substance, to keep the material from being exposed to the surrounding environment. To

put the antibiotics in the coating would be counter to Grimm's purpose. A modification that is counter to the purpose of a prior art reference does not provide adequate motivation for an obviousness rejection (MPEP § 2143.01V "If a proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984)). Cohan is silent regarding a therapeutic bioactive agent. For at least these reasons, the applicant submits that no *prima facie* case of obviousness has been made with respect to claims 24 and 25.

Moreover, according to the Examiner's arguments, Grimm and Cohan could have been used to reject claim 39 of Rogerson. Because the Examiner used Grimm and Cohan to reject applicant's claim 24, the Examiner would have similarly rejected claim 39 in Rogerson. Thus, the office action including the rejection should have been signed by the TC Director (See MPEP § 1003).

Applicant respectfully requests that the obviousness rejections be withdrawn.

Double Patenting Rejection

Claims 24-26 were rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 34 of U.S. Patent No. 6,565,885. Applicant respectfully requests that the Examiner hold this rejection in abeyance until the claims are determined otherwise to be allowable.

Please apply the one-month extension of time fee in the amount of 120.00 and any other required charges or credits to deposit account 06-1050.

Respectfully submitted,

Date: May 9, 2006

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Substitute Form PTO-1449 (Modified) U.S. Department of Commerce Patent and Trademark Office	Attorney's Docket No. 16614-030001	Application No. 10/612,393
Information Disclosure Statement by Applicant (Use several sheets if necessary) (37 CFR §1.98(b))	Applicant Thomas E. Tarara et al.	
	Filing Date July 3, 2003	Group Art Unit 1616

Examiner Initial	Desig. ID	Document
	C1	Advertisement for "Stop'n Grow" Manufactured by The Mentholatum Co. Ltd., East Kilbride Scotland G74 5P3
	C2	Agrimi, U. et al., "Amyloid, Amyloid-Inducers, Cytokines and Heavy Metals in Scrapie and Other Human and Animal Subacute Spongiform Encephalopathies: Some Hypotheses", *Med. Hypotheses* 40(2): 113-116 (1993)
	C3	Ahlneck et al., "The Molecular Basis of Moisture Effects on the Physical and Chemical Stability of Drugs in the Solid State", Int's J. Pharm. 62: 87-95 (1990)
	C4	Akers, M. J. et al., "Glycine Crystallization During Freezing: The Effects of Salt Form, pH, and Ionic Strength", *Pharmaceutical Research* 12(10):1457-1461 (1995)
	C5	Akoh et al., "One-stage synthesis of raffinose fatty acid polyesters", *J. Food Sci.* 52:1570-1576 (1987)
	C6	Alberts, B. et al., Molecular Biology of the Cell, 2nd ed., Garland Publishing, Inc., Ch. 2, page 58, (1989)
	C7	Aldous et al., "The Crystallization of Hydrates from Amorphous Carbohydrates", *Cryo-Letters* 16:181-186 (1995)
	C8	Allen, D. J. et al., "Determination of the Degree of Crystallinity in Solid-Solid Equilibria," *J. Pharm. Sci.* 58:1190-1193 (1969)
	C9	Allison, S. D. et al., "Mechanisms of Protection of Cationic Lipid-DNA Complexes During Lyophilization", *Journal of Pharmaceutical Sciences* 89(5): 682-691 (2000)
	C10	Allison, S. D. & Anchordoquy, Thomas J., *Lyophilization of Nonviral Gene Delivery Systems*, METHODS IN MOLECULAR MEDICINE, NONVIRAL VECTORS FOR GENE THERAPY, Ch. 18, 225-252 (Mark A. Findeis ed., Humana Press, 2001)
	C11	Altenbach et al., "Ca2+ Binding to Phosphatidycholine Bilayers As Studied by Deuterium Magnetic Resonance. Evidence for the Formulation of a Ca2+ Complex with Two Phosholipid Molecules" *Biochem.* 23:3913-3920 (1984)
	C12	Anchordoquy, Thomas J. et al., Physical Stabilization of DNA Based Therapeutics, 6(9) DDT 463-470 (May 2001)
	C13	Anekwe, J. et al., "Relaxation Constants as a Predictor of Protein Stabilization," *Biocalorimetry: Applications of Calorimetry in the Biological Science*, J. E. Ladbury and B. Z. Chowdhry, editors, John Wiley & Sons, pp. 243-251 (1998)
	C14	Babincova et al., "Dextran Enhances Calcium-Induced Aggregation of Phosphatidylserine Liposimes: Possible Implications for Exocytosis", *Physiol. Res.*, 48(4):319-321 (1999)
	C15	"Drug Absorption and Availability", Modern Pharmaceutics, 3rd edition, G. S. Banker et al. (eds), Marcel Dekker, Inc., pg. 145 (1996)
	C16	Bandara, G. et al., "Interarticular Expression of Biologically Active Interleukin 1-Receptor-Antagonist Protein by Ex Vivo Gene Transfer," *Proc. Natl. Acad. Sci.* 90:10764-10768 (November 1993)
	C17	Barnett, A. H. "Exhubera Inhaled Insulin: A Review", *Int. J. Clin. Pract.* 58(4): 394-401 (2004)
	C18	Bell, J. H. et al., "Dry Powder Aerosols I: A New Powder Inhalation Device," J. Pharm. Sci. 60(10): 1559-1564 (October 1971)
	C19	Belopol'skaya, T. V. et al., The Effect of Water as Natural Plasticizer on Thermal Properties of Denaturated DNA Studied by Calorimetry 4 VESTNIK SANKT-PETERSBURGSKOGO UNIVERSITETA SERIYA pp. 16-22, abstract only, 2 pgs. (1999)

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Other Documents (include Author, Title, Date, and Place of Publication)		
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	C20	Bigsbee et al., "Solid State Liability of Insulin: Comparison of Crystalline and Amorphous Forms," *Pharmaceutical Research* 10(10): Abstract No. PDD 7418, page S-279 (1993)
	C21	Blakeley et al., "Dry instant blood typing plate for bedside use," *Lancet*, 336: 854-855 (1990)
	C22	Bögelein, J. et al., "Influence of Amorphous Mannitol on Powder Properties of Spray Dried Trehalose/Dextran Mixtures", [on-line] [retrieved September 2005] Retrieved from the Internet <URL: http://www.pharmtech.unierlangen.de/APV 03 abs/bogelein.pdf > 2 pages (2003)
	C23	Bootsma, H.P.R. et al., "β-Cyclodextrin as an Excipient in Solid Oral Dosage Forms: In Vitro and In Vivo Evaluation of Spray-Dried Diazepan-β-Cyclodextrin Products," *International Journal of Pharmaceutics* 51:213-223 (1989)
	C24	Bosquillon, C. et al., "Aerosolization Properties, Surface Composition and Physical State of Spray-Dried Protein Powders", *Journal of Controlled Release* 99:357-367 (2004)
	C25	Branca, C. et al., "Destructuring effect of trehalose on the tetrahedral network of water: a Raman and neutron diffraction comparison", Physica A 304:314-318 (2002)
	C26	Branchu, S. et al. "The Effect of Cyclodextrins on Monomeric Protein Unfolding", *Biocalorimetry: Applications of Calorimetry in the Biological Science*, J. E. Ladbury and B.Z. Chowdhry (eds.), John Wiley &Sons, Ltd., 297-301 (1998)
	C27	Branchu, S. et al., "Hydroxypropyl-β-Cyclodextrin Inhibits Spray-Drying-Induced Inactivation of (β-Galactosidase", *Journal of Pharmaceutical Sciences* 88(9): 905-911 (1999)
	C28	Brange et al., "Chemical Stability of Insulin. I. Hydrolytic Degradation During Storage of Pharmaceutical Preparations," *Pharmaceutical Research* 9(6): 715-726 (1992)
	C29	Breitenbach, J. "Melt Extrusion: From Process to Drug Delivery Technology", *European Journal of Pharmaceutics and Biopharmaceutics* 54:107-117 (2002)
	C30	Broadhead, J. et al., "The Effect of Process and Formulation Variable on the Properties of Spray-Dried β-Galactosidase," *J. Pharm. Pharmacol.* 46(6):458-567 (June 1994)
	C31	Broadhead, J. et al., *The Spray Drying of Pharmaceuticals*, 18 Drug Development and Industrial Pharmacy 1169-1206 (1992)
	C32	Brown, "A Therapeutic Panorama of the Spongiform Encephalopathies", Antiviral Chem. Chemother. 1(2): 75-83 (1990)
	C33	Buckton et al., "The Use of Gravimetric Studies to Assess the Degree of Crystallinity of Predominantly Crystalline Powders", *Int. J. of Pharm.*, 123:265-271 (1995)
	C34	Buitink, Julia et al., *High Critical Temperature above Tg May Contribute to the Stability of Biological Systems* 79 BIOPHYSICAL JOURNAL 1119-1128 (August 2000)
	C35	Buldt et al., "Neutron Diffraction Studies on Phosphatidylcholine Model Membranes", *J. Mol. Biol.* 123:673-691 (1979)
	C36	Burvall et al., "Storage of Lactose-Hydrolised Dried Milk: Effect of Water Activity on the Protein Nutritional Value", *Journal of Dairy Research* 45: 381-389 (1978)
	C37	Byron, Peter R. et al., *Drug Carrier Selection - Important Physicochemical Characteristics* RESPIRATORY DRUG DELIVERY, 5th Edition, Interpharm Press, 103-113 (1996)
	C38	Byström et al., "Microcalorimetry - A Novel Technique for Characterization of Powders", *Respiratory Drug Delivery IV*, 297-302 (1994)
	C39	Carpenter, John F. et al., "Rational Design of Stable Lyophilized Protein Formulations: Some Practical Advice", *Pharmaceutical Res.* 14:8:969-975 (1997)

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	C40	Casselyn, M. et al., *Time-Resolved Scattering Investigations of Brome Mosaic Virus Microcrystals Appearance* D58 ACTH CRYST. 1568-1570 (2002)
	C41	Caughey et al., "Sulphated Polyanion Inhibition of Scrapie-Associated PrP Accumulation in Cultured Cells", *J. Virol.* 67(2): 643-650 (1993)
	C42	Cevc, G., "Membrane Electrostatics" *Biochim. Biophy. Acta.*, 1031(3):311-382 (1990)
	C43	Chan et al., "Formulation of Vaccine Ajuvant Muramyldipeptides (MDP). 1. Characterization of Amorphous and Crystalline Forms of a Muramyldipeptide Analogue", *Pharmaceutical Research* 5(8): 523-527 (1988)
	C44	Chan, Hak-Kim et al, "Solid State Characterization of Spray-Dried Powders of Recombinant Human Deoxyribonuclease (RhDNase)", *Journal of Pharmaceutical Sciences*, 87(5):647-654 (1998)
	C45	Chan, Hak-Kim et al., "Physical Stability of Salmon Calcitonin Spray-Dried Powders for Inhalation" *Journal of Pharmaceutical Sciences* 93(3): 792-804 (2004)
	C46	Chavan, V. et al., "Effect of Rise in Simulated Inspiratory Flow Rate and Carrier Particle Size on Powder Emptying From Dry Powder Inhalers", *AAPS Pharmsci 2000*; 2(2) article 10 [on-line] Retrieved from the Internet < URL: http://www.pharmsci.org > 7 pages (2000)
	C47	Chavan, V. et al., "Novel System to Investigate the Effects of Inhaled Volume and Rates of Rise in Simulated Inspiratory Air Flow on Fine Particle Output From a Dry Powder Inhaler", *AAPS Pharmasci 2002*; 4(2) article 6 [on-line] Retrieved from the Internet < URL: http://www.aapspharmsci.org > 6 pages (2002)
	C48	Chavan, V. S. et al., "Effect of Particle Size and Rise in Simulated Inspiratory Flow Rate on Device Emptying in a Dry Powder Inhaler System", [on-line] [retrieved 01/07/2005] Retrieved from the Internet <URL: htpp://www.aapspharmsci.org/abstracts/AM_1999/1001.htm > 1 page (1999)
	C49	Chawla et al, "Production of Spray Dried Salbutamol Sulphate for Use in Dry Powder Aerosol Formulation", *International Journal of Pharmaceutics* 108: 233-240 (1994)
	C50	Chiou et al., "Pharmaceutical Applications of Solid Dispersion Systems", *J. Pharm.* 60(9): 1281-1302 (1971)
	C51	Cleland et al, "The Development of Stable Protein Formulations: A Close Look at Protein Aggregation, Deamidation and Oxidation", *Critical Reviews in Therapeutic Drug Carrier Systems* 10(4): 307-377 (1993)
	C52	Cline, D. et al., "Predicting the Quality of Powders for Inhalation From Surface Energy and Area", *Pharmaceutical Research* 19(9):1274-1277 (2002)
	C53	Cline, D. et al., "Predicting the Quality of Powders for Inhalation", *Respiratory Drug Delivery VIII* 683-685 (2002)
	C54	Colaco et al., "Extraordinary Stability of Enzymes Dried in Trehalose: Simplified Molecular Biology," *Bio/Technology* 10: 1007-1011 (1992)
	C55	Colaco et al., "Trehalose Stabilization of Biological Molecules", *Biotechnol. Internat.*, pp. 345, 347-350 (1992)
	C56	Colaco et al., "Chapter 14: Chemistry of Protein Stabilization by Trehalose", *ACS Symposium Series 567, Formulation and Delivery of Proteins and Peptides*, J.L. Cleland & R. Langer, pp. 222-240 (1994)
	C57	Considine, G. D. et al, Van Nostrand's Scientific Encyclopedia, 9th edition, Volume 2, Wiley-Interscience, John Wiley & Sons, Inc., Definition of Vaccines: pp. 3591-3592 (2002)

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	C58	Costantino et al., "Moisture-Induced Aggregation of Lyophilized Insulin", *Pharmaceutical Research* 11(1): 21-29 (1994)
	C59	Costantino, H. R. et al., "Effect of Mannitol Crystallization on the Stability and Aerosol Performance of a Spray-Dried Pharmaceutical Protein, Recombinant Humanized Anti-IgE Monoclonal Antibody", *Journal of Pharmaceutical Sciences* 87(11):1406-1411 (1998)
	C60	Craig, I. D. et al., "Maillard Reaction Kinetics in Model Preservation Systems in the Vicinity of the Glass Transition: Experiment and Theory", *J. Agric. Food Chem.* 49(10):4706-4712 (2001)
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Information Disclosure Statement by Applicant (Use several sheets if necessary)		Applicant Thomas E. Tarara et al.	
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Information Disclosure Statement by Applicant (Use several sheets if necessary) (37 CFR §1.98(b))		Applicant Thomas E. Tarara et al.	
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